

Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

United States Court of Appeals for the Federal Circuit

IN RE: CELLECT, LLC,
Appellant

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457

CELLECT, LLC'S REPLY BRIEF

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CERTIFICATE OF INTEREST

Counsel for Cellect, LLC certifies the following:

1. The full name of every entity represented by us is:

Cellect, LLC.

2. The name of the real party in interest for the entity. Do not list the real party if it is the same as the entity:

Not applicable.

3. All parent corporations and any other publicly held companies that own 10 percent or more of the stock of the party or amicus curia represented by me are listed below:

Cellect, LLC is a wholly-owned subsidiary of Micro Imaging Solutions LLC.

4. The names of all law firms, and the partners or associates that have not entered an appearance in the appeal, and (a) appeared for the entity in the lower tribunal; or (b) are expected to appear for the entity in this court:

Not applicable.

5. Other than the originating case number(s), the title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal:

- *In Re: Cellect, LLC*, No. 22-1292 (Fed. Cir.); and
- *Cellect, LLC v. Samsung Electronics Co., Ltd., et al.*, No. 1:19-cv-00438 (D. Colo.).

6. All information required by Fed. R. App. P. 26.1(b) and (c) in criminal cases and bankruptcy cases.

None.

Dated: October 18, 2022

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TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
ARGUMENT	3
I. THE PATENT OFFICE EMBRACED THE BOARD'S LEGALLY ERRONEOUS INTERPRETATION OF THE PATENT ACT.....	3
A. The Statutory Language and Congressional Intent Confirm That PTA and PTE Should Be Treated the Same for Purposes of Double Patenting.....	3
B. The Patent Office Repeatedly Relies on the Wrong Case Law	10
D. The Double Patenting Doctrine Should Not Be Unmoored from the Equitable Considerations that Govern It.....	14
C. The Patent Office Improperly Attempts to Promulgate New Procedure Using this Case	17
II. THE UNDISPUTED EVIDENCE DEMONSTRATES THAT EXAMINER RAO CONSIDERED DOUBLE PATENTING	19
III. PATENTS SHOULD NOT BE INVALIDATED SOLELY DUE TO USPTO DELAYS	21
IV. THE PATENT OFFICE AGREES ITS INVALIDITY ALLEGATIONS RISE AND FALL WITH THE BOARD'S MISINTERPRETATION OF THE PATENT ACT.....	23
CONCLUSION	23

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust,</i> 764 F.3d 1366 (Fed. Cir. 2014)	11
<i>Amgen, Inc. v. Sandoz Inc.,</i> No. 18-11026 (MAS) (DEA), 2021 WL 5366800 (D.N.J. Sept. 20, 2021)	12, 14
<i>In re Berg,</i> 140 F.3d 1428 (Fed. Cir. 1998)	15
<i>Gilead Scis., Inc. v. Natco Pharma Ltd.,</i> 753 F.3d 1208 (Fed. Cir. 2014)	11, 15
<i>Microsoft Corp. v. I4I Ltd. P'ship,</i> 564 U.S. 91 (2011).....	20
<i>Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.,</i> 533 F. Supp. 3d 170 (D.N.J. 2021).....	12, 13, 14
<i>Novartis AG v. Ezra Ventures, LLC,</i> 909 F.3d 1367 (Fed. Cir. 2018)	<i>passim</i>
<i>Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.,</i> 909 F.3d 1355 (Fed. Cir. 2018)	15
Statutes	
35 U.S.C.	
§ 2(b)(2)	18
§ 103.....	23
§ 154.....	<i>passim</i>
§ 156.....	3, 11, 16
Other Authorities	
H.R. Rep. 106-287(I) (1999).....	6, 8, 14

Manual of Patent Examining Procedure (June 2020) § 609	20
Manual of Patent Examining Procedure (June 2020) § 609.02.....	20
Manual of Patent Examining Procedure (June 2020) § 804	7, 10

INTRODUCTION¹

Apparent from Director’s Response Brief on behalf of the Patent Office (Dkt. No. 62, “Resp.”), the Patent Office seeks to ignore, by administrative fiat, statutes enacted by Congress and disregard facially comprehensive initial examination of applications by the Examining Corps. It further attempts to change the law of obviousness-type double patenting as well as continuing application practice, contrary to existing law and policy.

The Patent Office doubles down on every aspect of the Board’s Decisions invalidating Cellect’s Challenged Patents (the ’742 Patent, ’369 Patent, ’626 Patent, and ’621 Patent), and studiously ignores the issue of statutory interpretation raised before this Court. Tellingly, the Patent Office does not even acknowledge statutory interpretation as an issue or the *de novo* review applicable to the Board’s misinterpretation. *See* Resp. at 5, 22-23. In fact, it fails to engage with many of Cellect’s arguments, opting instead to repeat the Board’s conclusory arguments without amplification.

For example, the Patent Office fails to address that the Board’s Decisions contradict Congress’ expressed goals for the two types of patent term restoration, PTA and PTE, and tortures the plain language of the PTA statute, 35 U.S.C.

¹ Unless otherwise noted, all abbreviations herein are defined in Cellect’s Opening Brief (Dkt. No. 22, “Br.”).

§ 154(b), without explaining what alleged ambiguity in the statute justifies the Board’s blatant departure from its actual text. Its superficial argument that Congress is presumed to legislate against the backdrop of existing jurisprudence is wholly inadequate to justify rewriting the statute.

The Patent Office also fails to distinguish its rewritten version of § 154(b) in light of this Court’s guidance in *Novartis AG v. Ezra Ventures, LLC*, 909 F.3d 1367 (Fed. Cir. 2018) which was not limited to a holding on how to treat PTE for purposes of double patenting, but rather explained how the judicial doctrine of double patenting could not trump a statutory award of additional patent term.

Moreover, the Patent Office reveals its faulty reasoning and agenda by counseling that patent owners should preemptively take terminal disclaimers on all continuation applications that mature into patents under the assumption that double patenting applies, regardless of whether a double patenting rejection exists or was never made during examination. Resp. at 29. This position is both nonsensical, inappropriate, and reflects the Patent Office’s erroneous belief that an award of PTA is itself an “unjustified timewise extension.” *Id.* at 23.

For at least these reasons, the Board’s Decisions should be reversed.

ARGUMENT

I. THE PATENT OFFICE EMBRACED THE BOARD’ S LEGALLY ERRONEOUS INTERPRETATION OF THE PATENT ACT

A. The Statutory Language and Congressional Intent Confirm That PTA and PTE Should Be Treated the Same for Purposes of Double Patenting

The Patent Office does not wrestle with the actual text of the PTA and PTE statutes, nor address that Congress had the same goals in mind when developing its two “technical” term restoration provisions. *See Br.* at 22-24 (explaining Congressional intent), 26-32 (explaining most logical reading of statutory frameworks), 39-41 (explaining inconsistencies under Board’s interpretation). It also improperly dismisses this Court’s guidance in *Novartis*, in favor of relying on inapposite decisions. As explained below, the Patent Office’s misinterpretation is unsupported.

Both PTA and PTE are granted by statutory authority. As a “[g]uarantee of prompt patent and trademark office responses . . . if the issue of an original patent is delayed due to the failure of the [Patent Office]” to adhere to certain deadlines for timely prosecution, then “the term of the patent ***shall*** be extended 1 day for each day” of delay. 35 U.S.C. § 154(b)(1)(A); *see also* 35 U.S.C. § 156(c) (“[t]he term of a patent eligible for extension . . . ***shall*** be extended by the time equal to the regulatory review period for the approved product . . .”) (all emphases added).

The PTA statute includes a limitation at § 154(b)(2)(B), which states that “No

patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.” 35 U.S.C. § 154(b)(2)(B).

The Patent Office does not meaningfully address the fact that the plain language of the PTA statute limits only patents with an *existing* terminal disclaimer from recapturing disclaimed term due to a grant of PTA. 35 U.S.C. § 154(b)(2)(B); Br. at 26-32. Simply put, § 154(b)(2)(B) refers to a patent “the term of which has been disclaimed beyond a specified date” that cannot be subject to a further adjustment that goes beyond the disclaimed date. 35 U.S.C. § 154(b)(2)(B). Contrary to the Patent Office’s repeated suggestion, § 154(b)(2)(B) does not address patents that lack such disclaimers—merely saying so does not make it true. As a result, there is no support in the statute for the Board’s position that patents with no existing disclaimer—especially related patents—should be invalidated solely because the PTA extended the expiration date, based on a new double patenting analysis. *Id.*

The Patent Office ignores the fact that Congress did not expressly invoke double patenting with respect to PTA, and instead rewrites this provision to allegedly mean that receiving a PTA alone can create a double patenting issue. But it tacitly concedes that its interpretation is unsupported in the statutory text when it argues that Congress intended to address double patenting by proxy. Resp. at 30;

see also Appx14, Appx37, Appx63, Appx87 (Board’s Decisions conceding same).

In fact, Congress explained in § 154(b)(2)(B) how PTA would be applied to a patent that already was subject to terminal disclaimer. There is simply no mention, express or implied, of applying double patenting in the PTA statute. It says nothing more than that any award of PTA cannot extend beyond the already disclaimed term of the patent. 35 U.S.C. § 154(b)(2)(B).

The Patent Office makes additional unavailing, superficial arguments that do not support its tortured reading of §154(b)(2)(B). First, the throwaway justification that Congress is presumed to legislate against the backdrop of existing jurisprudence only supports Cellect. *See* Resp. at 30. Given that Congress was well-aware of double patenting jurisprudence, it surely would have invoked that doctrine if it intended to do so. This generic observation does not justify the Patent Office’s position that Congress wrote “terminal disclaimer” while intending “double patenting.” Second, terminal disclaimers and double patenting may be related, but they are simply not interchangeable terminology. Br. at 29-30. As the Board admitted, terminal disclaimers may arise independently of double patenting. *Id.* (citing Appx14, Appx37, Appx63, Appx87 (Board’s Decisions) (“terminal disclaimers arise **almost** exclusively to overcome obviousness-type double patenting”) (emphasis added)). As Cellect explained, since terminal disclaimers may also arise independently of double patenting, it makes no sense to read the

term “terminal disclaimer” to mean “double patenting.”² Br. at 30. The Patent Office does not address the fact that the Board selectively chooses not to read other circumstances for terminal disclaimers into the statute. Thus, the Board’s misinterpretation creates ambiguity in the language of the statute. *Id.*

The Patent Office also does not challenge that the shared Congressional goals underlying PTA and PTE demonstrate that these two frameworks should receive comparable treatment for double patenting purposes. *Id.* at 22-25. Congress created PTA to “guarantee” patent term and “compensate patent applicants for certain reductions in patent term that are not the fault of the applicant.” *Id.* at 42 (citing H.R. Rep. 106-287(I) (1999) at 48-49). The Patent Office also concedes the legislative history that demonstrates Congress explicitly stated that “[o]nly those who purposely manipulate the system” should be penalized by loss of term. *Id.* This alone debunks the Patent Office’s bedrock assumption that PTA itself is an “unjustified timewise extension.” Resp. at 23.

Remarkably, the Patent Office’s Response does not directly address the Congressional intent behind 35 U.S.C. § 154(b). *See generally id.* at 30-36. It ignores the conflict between the Board’s Decisions and these goals—mandatory adjustments to patent term enacted by Congress and codified in Title 35—

² For example, an applicant may file a disclaimer to expedite prosecution of a continuation application despite no double patenting rejection.

summarily rejected by the Board and now the Patent Office. Strangely, the Patent Office refers to Congress’ explanation of intent for the award of PTA as a “red herring” (Resp. at 33), though it is unclear how the Congressional intent behind the statute whose interpretation is at issue could possibly be labeled a distraction.

After refusing to recognize the statutory text and Congress’ intent, the Patent Office misuses this Court’s decisions in *Gilead* and *AbbVie* to purportedly justify treating PTA and PTE differently for purposes of double patenting—namely, to use the mandatory award of PTA to make a patent into a double patenting reference against related patents, without doing the same for PTE. Resp. at 29, 31, 33. As pointed out in Cellect’s opening brief (Br. at 25 n.2, 37-38, 43) and as explained in detail *infra*, Section I(B), *Gilead* and *AbbVie* predate *Novartis*, in which this Court determined that a patent with a different expiration date solely due to PTE should not be a double patenting reference against a related patent. See *Novartis*, 909 F.3d at 1375. Additionally, these cases involve a different factual scenario than here. Unlike here, in *Gilead* and *AbbVie*, double patenting concerns arose from two patents with overlapping subject matter and *different* priority dates, thereby providing the opportunity for gamesmanship and improper extension of patent term that the double patenting doctrine exists to address. See Manual of Patent Examining Procedure (June 2020) (“MPEP”) § 804 (defining purpose of double patenting).

Indeed, the Patent Office gives *Novartis* short shrift and pays no heed to this Court’s guidance on resisting the addition of language that was not expressed in the PTE statute. Instead, it contrives an argument that because the PTE statute does not have the same limitation about terminally disclaimed patents, it must somehow mean that double patenting applies based on PTA but not PTE. Resp. at 25-27, 28-32. But the simple fact that the PTA statute and the PTE statute each has different limitations on its applicability only reflects that they are different forms of statutory adjustments to patent term. That difference does not support the Board’s decision to apply disparate treatment to PTA and PTE with respect to double patenting.

As this Court explained in *Novartis*, following a detailed evaluation of both PTA and PTE, a patent should not be at risk of invalidation for double patenting just because “the term extension it received causes the [extended] patent to expire after [another] allegedly patentably indistinct . . . patent.” *Novartis*, 909 F.3d at 1373. The Court acknowledged the differences between PTA and PTE, but also explained that they both exist to “restore the value of the patent term that a patent owner loses during the early years of the patent” *Id.* at 1369; *see also* H.R. Rep. 106-287(I) (1999) at 49-50. Thus, the *Novartis* holding that “a judge-made doctrine” should not “cut off a statutorily-authorized time extension” applies equally to PTA and PTE. *Novartis*, 909 F.3d at 1375.

Moreover, as Cellect explained, this Court in *Novartis* not only held that patents should not be invalidated due to double patenting solely based on PTE; it also cautioned that the limitations on PTE should not be expanded beyond the plain text of the statute. Br. at 31-32. This Court dismissed defendant's alleged concerns that applying PTE to one patent might "effectively" extend term for another patent, because the limitations around use of PTE did not explicitly forbid such an effective extension. *Id.* at 32. This Court should reject the Patent Office's attempt here to broaden the limitations on PTA beyond the statutory text as well, consistent with the guidance in *Novartis*.

Having failed to establish, as a matter of statutory language or case law, that an award of PTA alone invokes application of double patenting, the Patent Office also failed to rebut Cellect's explanation that differential treatment of PTA and PTE for purposes of double patenting will create confusion and inconsistent results. See *id.* at 40. For example, the Patent Office does not address the issues that arise when evaluating a patent with both PTE and PTA. It merely points in conclusory fashion to this Court's decision in *Novartis* that a patent that should have been disclaimed without considering its PTE could be invalidated due to double patenting. Resp. at 30-31. But the Patent Office's argument is circular because it assumes the conclusion that the Patent Office desires, which is that a difference in expiration dates due solely to PTA is a per se "unjust timewise extension" and thus

a sufficient basis for requiring a terminal disclaimer in an otherwise valid patent.

Id. As Cellect explained, this is inconsistent with *Novartis*.

B. The Patent Office Repeatedly Relies on the Wrong Case Law

The Patent Office relies on case law inapposite to this case, while improperly dismissing the sound reasoning of two jurists who considered this exact issue. *See, e.g.*, Resp. at 24-29, 31-34. In addition, the Patent Office mischaracterizes the treatment of PTA and double patenting by these two district courts. *Id.* at 31-32.

The Patent Office focuses heavily on this Court’s holdings in *Gilead* and *AbbVie*, but these cases do not control here for several reasons. *See, e.g., id.* at 24-29, 31, 33-34. As a threshold matter and as Cellect has pointed out throughout these proceedings, both these cases dealt with **unrelated** patents. As the Court and the Patent Office are well aware, when overlapping subject matter is contained in two patents with different priority dates, then a possibility may exist for concerns about gamesmanship and unjust timewise extensions that the double patenting doctrine is intended to address. MPEP § 804. However, that scenario is not present for any of the patents in this appeal, and this renders those cases inapposite here.

Further, in *Gilead*, this Court found that the applicant engaged in “potential gamesmanship . . . through structuring of priority claims,” filing multiple unrelated

patents on the same invention. *Novartis*, 909 F.3d at 1374-75 (discussing rationale for its holding in *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1211-12, 1217 (Fed. Cir. 2014)). Similarly, *AbbVie* also involved patents with different priority dates. As a result, in *AbbVie*, the Court found that the applicant also chose to file “separate applications for overlapping subject matter.” *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1373-74 (Fed. Cir. 2014) (“We hold that [applicant] is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct.”). Such is not the case here, where all of Cellect’s Patents at Issue claim the same priority date, and the Board weaponized Cellect’s patents against their relatives. Moreover, neither *Gilead* nor *AbbVie* expressed a holding about PTA.

Further, *Gilead* and *AbbVie* predate *Novartis*, and thus lacked the benefit of this Court’s reasoning with respect to the parallel statutory framework for PTE and *Novartis’* policy rule that the judicially created double patenting doctrine cannot cut off a statutorily authorized extension. Accordingly, the Court’s opinions in *Gilead* and *AbbVie* do not discuss § 156 in any detail, much less address its relationship to and construction with § 154. Indeed, *AbbVie* does not even mention it. In particular, those cases also could not and did not consider this Court’s recent

guidance plainly stating that the “judge-made doctrine” of double patenting should not “cut off a statutorily-authorized time extension.” *Novartis*, 909 F.3d at 1375.

Confronted with two recent district court decisions that had the benefit of *Gilead*, *AbbVie*, and *Novartis*, which faced the exact scenario here of related patents with different expiration dates due solely to statutorily-authorized changes to patent term, and where the two district courts came to the only conclusion supported by the controlling statutes and case law—namely, that PTA alone does not create double patenting reference that invalidates related patents—the Patent Office mischaracterizes and dismisses the district court decisions.

The Patent Office is simply wrong that the facts here are somehow different than the facts in the district court cases *Amgen* and *Mitsubishi*. For example, the Patent Office attempts to distinguish these cases because “the challenged patent was the earlier filed, earlier issued, but later expiring patent.” Resp. at 32. This is precisely the point. In *Amgen*, the challenged patent was later-expiring solely due to receiving both PTA and PTE. *Amgen, Inc. v. Sandoz Inc.*, No. 18-11026 (MAS) (DEA), 2021 WL 5366800, at *26-27 (D.N.J. Sept. 20, 2021). The District Court of New Jersey, applying *Novartis* and considering the equities, found the statutory term restorations could not create a basis for double patenting. *Id.* at *27.

In *Mitsubishi*, as for Cellect, the challenged patent and reference patent claimed priority to the same application, but the challenged patent expired later

solely due to PTA. *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170, 211-212 (D.N.J. 2021). But for PTA, the patents would have shared the same expiration date. Applying *Novartis*, the court found that it was inappropriate to use PTA to create a double patenting reference. *Id.* at 214.

Just as in these cases, Cellect's various Challenged Patents expired later than the alleged reference patents solely due to PTA. To the extent the Patent Office argues that the filing and issuance dates somehow distinguish these cases (*see* Resp. at 32), Cellect matches that fact pattern too. Cellect's challenged '369 Patent was earlier-filed and earlier-issued relative to its alleged invalidating reference, the '036 Patent. *See* Br. at 6, 12. The '369 Patent expired later than the '036 Patent solely due to PTA, but the Board invalidated it regardless. Similarly, Cellect's challenged '626 Patent issued earlier than its alleged invalidating reference, the '369 Patent. *See id.* at 5, 12. However, the '626 Patent received 14 days more PTA than the '369 Patent, and for that reason alone it expired later and the Board invalidated it. *Id.* at 12. Thus, whatever distinction the Patent Office is trying to draw does not exist. The manner in which these district courts have interpreted this Court's guidance in *Novartis* is logical and consistent, and should apply here.

D. The Double Patenting Doctrine Should Not Be Unmoored from the Equitable Considerations that Govern It

Because the Patents at Issue are related and only expire on different dates due to statutorily-mandated PTA, it is nonsensical to state, as the Patent Office does, that Cellect sought or obtained an unjust timewise extension. Neither Cellect, nor any patentee, has control over the PTA statute which dictates what PTA, if any, the Patent Office must award. To repeatedly characterize this scenario as an unjust timewise extension lacks credulity as well as ignores the supremacy of Title 35 over a judicial doctrine. The doctrine of double patenting should not be over-extended to cover the Patents at Issue because, *inter alia*, it would be inconsistent with Congressional intent and the policies underlying the doctrine, as explained above.

The Patent Office misstates Cellect’s argument to assert that Cellect seeks to add “a predicate showing by clear evidence” of gamesmanship to each individual double patenting analysis. Resp. at 33. That is not the case. Rather, Cellect’s policy argument, which the Patent Office does not engage with, is that expansion of the double patenting doctrine makes no sense when the doctrine was designed to address gamesmanship (*see, e.g., Mitsubishi*, 533 F. Supp. 3d at 214, *Amgen*, 2021 WL 5366800, at *27), and when Congress specifically included in the legislative history that only purposeful manipulation should result in penalty. *See H.R. Rep. 106-287(I) (1999)* at 48-49.

The Patent Office’s position begs the question of why it seeks to invoke the double patenting doctrine if it agrees there is no gamesmanship, particularly given that precluding gamesmanship is the entire purpose of the doctrine. Indeed, the Patent Office claims that this Court’s “cases did not limit the ODP doctrine to such scenarios,” *i.e.*, scenarios involving gamesmanship during prosecution. Resp. at 33. But that is exactly what double patenting is limited to, because that is the situation double patenting was created to address. *See, e.g., Novartis*, 909 F.3d at 1375 (award of PTE raises “no concern that [patent owner], once its [] patent issued, sought to subsequently secur[e] a second, later expiring patent for the same invention”) (internal quotation omitted); *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355, 1364 (Fed. Cir. 2018) (double patenting inapplicable when difference in expiration dates is due to “happenstance,” not “prosecution gamesmanship”); *Gilead*, 753 F.3d at 1210 (double patenting applies when patent owner structured priority claims to achieve extra term). As this Court has recognized, double patenting is a “judge-made doctrine that prevents an extension of the patent right beyond the *statutory* time limit”—statutory extensions do not create an improper extension. *In re Berg*, 140 F.3d 1428, 1431-32 (Fed. Cir. 1998) (emphasis added).

Moreover, the Patent Office claims that the “the doctrine is designed to prevent an inventor from securing a second, later expiring patent for the same

invention,” but seeking such a patent on the same invention *is* gamesmanship. Resp. at 33-34. In contrast, here, the only reason that the alleged reference patents expire later than the Challenged Patents is PTA.³ The inventor did not act to “secur[e]” such a patent—the Patent Office assigned a different expiration date to it based on its own delays. This Court said as much in *Novartis*: “but for” the § 156 extension, the challenged patent would have expired before the alleged reference, so there was “no concern” that patent owner “sought to subsequently secure a second, later-expiring patent for the same invention.” *Novartis*, 909 F.3d at 1375 (internal quotation marks and citation omitted). It is the same here: but for the § 154(b) adjustment, the challenged patent would have expired on the same date as the alleged reference, such that there is no concern that the patent owner sought a second, later-expiring patent.

The Patent Office reiterates its theory that a risk of harassment through divided ownership is another basis to invoke double patenting, even where the record is bereft of any indication, suggestion, or even remote possibility of such divided ownership. Resp. at 36. Here, the Patent Office simply repeats, without support, the Board’s conclusion that a bankruptcy proceeding *could* split Cellect’s expired patents, allegedly justifying a risk of harassment by multiple owners. *Id.*

³ The Patent Office appears to drop the Board’s backstop position that a patent expiring on the same day as another patent may invalidate it. See Br. at 44-45 (pointing out the infirmities of such an analysis).

Such a scenario is highly speculative and contrived, which the Patent Office simply ignores—and such a situation would exist, at least theoretically, with respect to every single entity that owns related patents. It is telling that this single, speculative circumstance is the only one the Board and the Patent Office could invent that might not be resolved by Mr. Adair’s declaration that Cellect will never split its related patents amongst multiple owners. Br. at 44 (citing Appx1753 (Adair Decl.), ¶ 24). To add yet another layer of speculation, neither the Patent Office nor Board attempted to explain why a bankruptcy court would for some reason consider splitting **related** (and expired) patents amongst multiple owners, particularly where the record demonstrates that the patents are licensed. *See, e.g.*, Appx1752-1753 (Mr. Adair’s declaration), ¶¶ 23-24 (Cellect may not freely assign the patents because it has certain existing exclusive licenses). The alleged risk of potential harassment by multiple owners is not gamesmanship and too tenuous to support the Patent Office’s position and warrant an invalidating double patenting rejection.

C. The Patent Office Improperly Attempts to Promulgate New Procedure Using this Case

In essence, the Patent Office seeks to create another level of review, which is nowhere authorized or suggested in Title 35, 37 C.F.R., nor the MPEP, to require patent applicants to re-examine double patenting based purely on term adjustment through no fault of the patent owner, even though a patent has already been

allowed and the patent owner has already paid the issue fee. The Patent Office’s statement that patent owners should take a preemptive terminal disclaimer practice “to heart” exemplifies the Patent Office’s faulty reasoning. Resp. at 29. With this cavalier and paradigm-shifting position, the Patent Office seeks to upend decades of continuation practice to posit that patent applicants should *assume* their related continuation patents are patentably indistinct and take an unnecessary terminal disclaimer to avoid complete invalidation in case any PTA is assigned, despite receiving no such objection from the actual examiner. Not only is this contrary to Congressional intent, as explained above, as an administrative agency such as the Patent Office cannot use this re-examination proceeding to create new (and unreasonable) procedures contrary to existing statutory and regulatory authority.

*See 35 U.S.C. § 2(b)(2) (Patent Office “may establish regulations, **not inconsistent with law**”)* (emphasis added).

The Patent Office’s position is not only problematic because it is legally deficient, but it also weaponizes PTA by the very agency that is the source of awarding it. PTA was supposed to be a term restoration and compensation to the applicant for loss of term due to Patent Office delay. For the Patent Office to advocate that it may invalidate continuation patents solely because it is required to award PTA based on its own actions, and that such a result is required by the

existing statutory and case law regime, stands both such regimes on their heads and should be summarily rejected for this reason alone.

II. THE UNDISPUTED EVIDENCE DEMONSTRATES THAT EXAMINER RAO CONSIDERED DOUBLE PATENTING

The Patent Office does not dispute any of the facts that demonstrate Examiner Rao considered potential double patenting issues during prosecution of the Challenged Patents—including issuing a double patenting rejection when warranted for a different application in the same family. *See* Br. at 10-17, 45-52; Resp. at 36-38. The Patent Office attempts to dodge this evidence by not addressing it and offering generic arguments about when a substantial new question might be appropriate. But the Patent Office is unable to explain why a substantial new question exists here, other than the bald assertion that the evidence is insufficient. Like the Board, the Patent Office similarly ignores the unrebutted testimony of Mr. Spar, Cellect’s expert on Patent Office examination practice, who opined that Examiner Rao addressed double patenting based on his search strategies and other signs of diligence. Br. at 47 (citing Appx2441-2443, Appx8110-8113, Appx10912-10915).

The Patent Office claims that it cannot presume Examiner Rao considered the family members of the Challenged Patents during prosecution, but its claim falls flat for two reasons. *See* Resp. at 36-37. First, Examiner Rao’s consideration of *related* patents is at issue here—not consideration of miscellaneous cited

references to unrelated material. Indeed, as Cellect explained, the MPEP *required* Examiner Rao to fully consider such related patents. Br. at 48 (citing MPEP § 609.02). The Patent Office ignores both this provision and the evidence that Examiner Rao complied with it. *See id.* at 47-48.

Second, the Examiner took a range of affirmative actions that demonstrate he considered the other patents in the family, such as identifying them in his chosen search terms and in his notes of search results, signing his initials next to them in information disclosure statements which explicitly indicates consideration (see MPEP § 609), performing an inventor name search, and considering the applicability of some of the same alleged prior art across multiple prosecutions. *See* Br. at 46-51. This Court need not presume that Examiner Rao considered double patenting—the undisputed evidence proves that he did, and nothing in the record suggests that Examiner Rao somehow did not perform his duties. *See also Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 97 (2011) (“[Section] 282 codified ‘the existing presumption of validity of patents,’ . . . [capturing] a common-law presumption based on ‘the basic proposition that a government agency such as the PTO [is] presumed to do its job.’”) (citations omitted).

Further, the Patent Office concedes that Examiner Rao knew about the PTAs during prosecution of the Challenged Patents, contrary to the Board’s assertion. Resp. at 38 n.5. This admission eliminates a pillar of the Board’s argument for

why a substantial new question of patentability existed for at least the '742 Patent. *See Appx21-22, Appx46, Appx70-71, Appx94-95.* The Patent Office ignores the impact of the Board's error. Congress could not have intended such a shifting sands approach and its arbitrary results. Instead, the Patent Office falls back on the cursory and erroneous statement that "at bottom, there was no evidence" Examiner Rao considered double patenting. Resp. at 38 n.5. As shown above and in Cellect's Opening Brief, this assertion is simply wrong. No substantial new question of patentability exists here.

Finally, the Patent Office fails to respond to Cellect's explanation that if PTA can create a substantial new question of patentability among related patents, it creates a shifting sands approach to prosecution and invalidation. Br. at 51-52. Specifically, one patent receiving even one day more or less of PTA than its relative could change the entire double patenting analysis that the Patent Office proposes. Congress cannot have intended such arbitrary results.

III. PATENTS SHOULD NOT BE INVALIDATED SOLELY DUE TO USPTO DELAYS

If this Court allows the judicially created doctrine of double patenting to include patents whose expiration dates differ solely because of congressionally mandated term adjustments, it should invalidate only the change to the patent's

term.⁴ Cellect does not speak simply for itself, contrary to the Patent Office’s attempt to narrow this issue. *See* Resp. at 38. Patent owners should generally have the option to decline a term adjustment when facing double patenting objections after issuance, so that they need not forfeit an otherwise valid patent. In fact, a terminal disclaimer is available to patent owners to do just that if their patents are unexpired. In circumstances like Cellect’s where the challenged patents are expired, if the law is changed to apply double patenting based on continuations, then patent owners should have the same option.

The Patent Office cannot support its punitive position that an entire patent should be invalidated because it assigned that patent additional term due to its own delays and created a double patenting reference. Indeed, the Patent Office repeatedly argues that it is this change in patent term that is somehow unjust. But its so-called solution far exceeds the scope of the alleged problem. Thus, invalidation of the entire patent makes no sense. The Patent Office proposes to give with one hand (by restoring term lost to the Patent Office’s own delays) and

⁴ Contrary to the Patent Office’s assertion, Cellect’s argument is not new. Resp. at 38. Cellect made detailed arguments to the Board explaining the ramifications of the Patent Office’s untenable position. *See, e.g.,* Appx4016-4019; Appx4120-4123. Cellect explained that the logical reading of the PTA statute indicates that PTA was never intended to invalidate an entire patent, and if anything, “Section 154(b)(2)(B) would limit the adjustment to the adjusted term it disclaimed over, rather than invalidate.” Appx4123; *see also id.*, Appx4122 (“double patenting was not intended to invalidate a patent in this circumstance”).

simultaneously take with the other (by using that restoration as the sole basis for invalidation).

IV. THE PATENT OFFICE AGREES ITS INVALIDITY ALLEGATIONS RISE AND FALL WITH THE BOARD'S MISINTERPRETATION OF THE PATENT ACT

The Patent Office does not dispute that the Board's invalidity grounds required a finding of double patenting against the '742 Patent, '369 Patent, and '626 Patent. Resp. at 39 ("Director does agree that Cellect's challenged patents rise or fall together based on the arguments Cellect raised"); *id.* at 40 (Board's affirmations involved either "the reference patent itself" or "the reference patent in combination with another reference"). Thus, because the double patenting doctrine does not apply here and the Board failed to assert any grounds that did not require a double patenting reference, the Board's invalidity arguments fail. Cellect's explanation of what a finding in its favor means in light of the Board's alleged invalidity grounds is not somehow a new argument. *Id.* at 39. It is simply the logical impact of reversing the Board's decision on double patenting. The Patent Office may not now create additional grounds based on 35 U.S.C. § 103 that allegedly do not require double patenting to justify the Board's orders.

CONCLUSION

The judgment should be reversed because double patenting does not apply to the Challenged Patents.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FED. CIR. R. 32

1. The foregoing filing complies with the type-volume limitation of Fed. Cir. R. 32(b)(1) because this brief contains 5,407 words exclusive of the parts of the filing as exempted by Fed. Cir. R. 32(b)(2).
2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2019 in Times New Roman 14 point font.

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